

U.S. Consumer Product Safety Commission

MEETING LOG

PRODUCT: Nanotechnology

SUBJECT: U.S. TAG to ISO/TC 229 (Nanotechnology) Virtual Meeting to Review November ISO/TC 229 Plenary Meetings

LOCATION: Teleconference

DATE: December 10, 2021

ENTRY DATE: December 29, 2021

LOG ENTRY SOURCE: Joanna Matheson (HSTR)

COMMISSION ATTENDEES: Joanna Matheson (HSTR)

NON-COMMISSION ATTENDEES: Contact ANSI for a complete list.

MEETING SUMMARY:

ISO Technical Committee 229 (ISO TC/229) focuses on standardization in the field of nanotechnologies, understanding and control of matter and processes at the nanoscale where the onset of size-dependent phenomena usually enables novel applications, as well as use of nanoscale materials to create improved materials, devices, and systems that exploit these new properties. Specific working groups address the development of standards and guides for terminology and nomenclature; metrology and instrumentation; test methodologies; modelling and simulations; and science-based health, safety, and environmental practices.

The focus of this virtual meeting was to review the discussions and actions from the November 2021 ISO/TC 229 Plenary meetings. The lead for each US TAG ISO/TC 229 working group provided a summary of the projects discussed by their working group experts at the November plenary meetings.

For working group 1, terminology and nomenclature, three standards were published, three standards balloted, and updates on projects for graphene terms were given. Meeting attendees expressed concern on some of the graphene terms, for example, stating that “graphene material” is too nebulous of a term and that non-graphene (such as graphite) materials could be included under that term. In addition, experts noted that some terms on cellulose nanomaterials needed to be updated and a definition was presented for individualized cellulose nanofibril. A project led by the U.S. on liposome terminology was accepted as a new work item. The project leaders suggested to revise the scope as it was possible to add other lipid-based nanomaterials to the document. Work continues on defining the term Advanced Material. An ANSI team will meet and come back with recommendations on potential needs for definitions relating to advanced materials and a strategy to gain clarity with the use of the term and related terms.

For working group 2, metrology and instrumentation, presentations were given on two new project proposals, both led by U.S. experts; *Total and free drug quantitation in doxorubicin hydrochloride liposomal formulations*, and, *Soxhlet extraction to remove polyaromatics and other organic contaminants from carbon nanomaterials*. The working group recommended to revise the ISO/TR 18196, *Measurement technique matrix for the characterization of nano-objects*, with no change to the existing scope, and for the preliminary work item proposal TS 23879 *Structural characterization of graphene oxide flakes: thickness and lateral size measurement using AFM and SEM* to move forward as a preliminary work item. Most comments, particularly the U.S. comment on the dynamic mass flow approach, were resolved for the ballot of ISO/DTR 24672 *Guidance on the measurement of nanoparticle number concentration*. Once two comments are resolved, the working group recommended the project leader to submit the revised draft for publication. Work continues on multiple projects including characterization of amorphous carbon content in carbon nanotubes, structural characterization of graphene - chemical vapor deposition (CVD) grown graphene, characterization of graphene in powders and suspensions, as well as material specifications for graphene - blank detail specification.

Working group 3's (health, safety and the environment) lead noted that four standards were published in 2021 as well as three submitted for publication. Documents in development include a more mature preliminary work item proposed project co-led by the U.S., *In vitro nanoparticle phototoxicity assay*. The updated draft was distributed for review and comment and working group experts recommended its moving forward to ISO/TC 229 as a new work item. This is similar for an evaluation method for chronic inhalation toxicity based on lung burden of nanomaterials. Once the scope is adjusted limiting the document scope to insoluble materials, the project was recommended for moving forward as a new work item. Other preliminary projects expected for completion in 2022 is a method measuring the lung burden of nanomaterials for inhalation toxicity studies. Clarification of the title and scope are expected to be resolved at the next project meeting. Scope refinement and document drafting is to occur for several preliminary work item proposals, including PWI 4963 *Radiotelemetry-spectral-echocardiography based real-time surveillance protocol for in vivo toxicity detection and monitoring of engineered nanomaterials (ENM)*, and the CPSC proposed project PWI 5265 *Method for characterizing and quantifying nanomaterials released from wood products* led by Treye Thomas. Inaugural meetings were held for two projects, one on extracting nanomaterials from tissue, and the second, on updating safety data sheets for nanomaterials. Presentations were given on four new project proposals that would assess toxicity of manufactured nanomaterials, monitor for nanomaterial-induced alteration of protein stability, characterize mRNA-containing nano-emulsions, and characterize bio-conjugated nano-gold suspensions. In addition, potential projects from the November meetings were noted, these projects would seek to harmonize tiered approaches and to develop guidance on recycling of nanomaterials.

Working group 4 (material specification) met for three days during the November meetings. The working group experts modified the working group's scope to: "Develops documents specifying relevant compositions, properties and characteristics of raw and intermediate manufactured nanomaterials." A new project was proposed by Korea on photocurable polymer resin containing nanocomposites for additive manufacturing. Two projects were recommended by the working group experts to move forward to new work items, *Nanocomposite materials for insulating: Specification of characteristics and measurement method*, and the U.S. led *Classification framework of commercial graphene*. Work continues on two silica projects, TS22298, *Silica nanomaterials – Specification of characteristics and measurement methods for nanostructured porous silica samples with ordered nanopore array (SONA)*, and PWI *Porous silica for chromatography*.

Working Group 5 (products and applications) met over the two weeks in November. A revised draft document was reviewed on TS 23367 *Performance Characteristics of Nanosensors for Chemical and*

Biomolecule Detection. The working group recommended that the project leader revise the title and submit the document to ISO/TC 229 for balloting. Similarly, PWI 10689 *Superhydrophobic surfaces and coatings: characteristics and performance assessment* revisions on the working draft were discussed and the working group recommended that the project leader submit the document to ISO/TC 229 for NWIP balloting. Updates to PWI 10818 *Textiles containing nanomaterials and nanostructures - superhydrophobic characteristics and durability assessment* were discussed and additional revisions recommended. For PWI 4971 *Performance Evaluation of Nanosuspension Containing Clay Nanoplates for Quorum Quenching*, the working group discussed the revised draft document and requested that the definition of “minimum bactericidal concentration” be modified as well as a definition added for the new term of “minimum bacteriostatic concentration”. In addition, the expert group recommended checking with ISO/TC 190 (Soil Quality) subcommittee for any overlap. The project leader for TR 23652 *Considerations for Radiolabeling Methods of Nanomaterials for Performance Evaluation* reviewed the revised draft and requested more expert comments since few were received. New terms were noted during the November meeting; the working group congener recommended that the project leader collaborate with Working Group 1 on defining the new terms. In the joint meeting with Working Group 3, PWI 23653 *The Overview Methods to Evaluate the Nanoparticle in Cellular Uptake Between 2-dimensional and 3-dimensional Cell Cultures* was cancelled due to the lack of project participants. The project leader narrowed the scope to focus on the cell penetration of nanoparticles and named the preliminary work item proposal as *Experimental Considerations when Evaluating Nanoparticle Performance of Cellular Uptake*). A revised document draft proposal was recommended by the joint working groups.